HDMA Testimony

Statement of the Healthcare Distribution Management Association

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Before the House Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources on "Pharmaceutical Supply Chain Security"

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Introduction

Mr. Chairman and Members of the Subcommittee, thank you for the invitation to provide the perspective of the Healthcare Distribution Management Association (HDMA) at this important hearing on the issue of "Pharmaceutical Supply Chain Security." I am John Gray, HDMA's President and CEO.

HDMA represents the nation's primary, full-service healthcare distributors. Our members include large national companies and regional, family-owned businesses. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 142,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system.

HDMA members serve as the central link in a sophisticated national supply chain. As such, we have a responsibility to work closely with our supply chain partners to safeguard patient safety. We take this mission very seriously, and we support manufacturers, pharmacies, law enforcement, regulators and legislators in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated. No one link in the supply chain works independently, and patients depend on our collective efforts to keep their medicine safe and secure.

Ongoing Supply Chain Improvements

There is no greater concern among HDMA members than the threat of counterfeit or adulterated pharmaceutical products in our healthcare system. Manufacturers, distributors, and pharmacies must remain vigilant in recognizing this increasingly sophisticated criminal threat, and must continually implement new systems, processes, and techniques to defeat it. While there is no single solution to the counterfeit threat, we believe any effective response must include:

1. strict regulation and enforcement;
2. adoption of new technologies;
3. business and government alliances to track and report counterfeit drugs; and
4. developing and implementing industry best practices.

1. Strict Regulation and Enforcement

HDMA advocated for the implementation of the Prescription Drug Marketing Act (PDMA) final rule as an important measure in the effort to combat counterfeit drugs. By implementing the Final Rule on December 1, 2006, we believe the FDA is taking an important step forward to further ensure patient safety, prescription drug integrity, and supply chain security. The pedigree provisions of the PDMA, however, are just one part of a comprehensive anti-counterfeiting strategy.

To that end, strong and consistent distributor licensure requirements are absolutely critical to ensure that criminals are **never** able to handle and distribute prescription medicines. Because the nation's drug distribution system is regulated at both the federal and state levels of government, HDMA proactively drafted a model state distributor

licensure bill two years ago with the goal of achieving uniform, tough standards on a state-by-state basis. We have worked closely with the National Association of Boards of Pharmacy (NABP) and manufacturer and pharmacy organizations to advocate for implementation of more uniform, tough standards. I am pleased that sixteen states have enacted tougher distributor licensing standards, including the chairman's home state of Indiana, and bills are pending in an additional 18 states.

HDMA is also a strong supporter of increasing criminal penalties for those involved in drug counterfeiting and medicine tampering. The current federal criminal penalties for those who are knowingly involved in the counterfeiting of prescription drugs are wholly inadequate given the potential harm that can result from fake or adulterated medicines. That is why HDMA has advocated for increasing criminal penalties and we support the "Counterfeit Drug Prevention Act" (HR 5156), introduced by Representatives Mike Rogers and Gene Green. HR 5156 would increase criminal penalties for counterfeiting prescription drugs from three years to 20 years, and life in prison if the counterfeiting results in death.

2. Adopting New Technologies

Anti-counterfeiting technologies can serve an important role in securing the nation's prescription drug supply; however, no single technology can absolutely prevent counterfeiting. Rather, a layering of various technologies can create a significant barrier to entry.

As those who seek to introduce counterfeit or adulterated products into the supply chain become more sophisticated, so, too, must the technologies that manufacturers, distributors and pharmacies employ to defeat them. Current and emerging technologies, such as those employing electronic product codes (EPC)/radio frequency identification (RFID), hold the most promise for tracking, tracing and authenticating a product's movement across the supply chain.

Using EPC/RFID technology, a tiny radio frequency chip containing essential data in the form of an electronic product code will allow supply chain stakeholders to track the chain of custody (or pedigree) of every unit of medication on an individual basis. By tying each unit to a unique electronic ID, products can be tracked electronically through the supply chain.

Tremendous progress is being made in the development and adoption of EPC/RFID technology in the pharmaceutical market. This is a monumental endeavor that requires close collaboration among all constituents of the healthcare supply chain. That is why HDMA will co-sponsor the second RFID Summit with the National Association of Chain Drug Stores to provide a forum for further education on the development and deployment of RFID technology. Moreover, many of our members are participating in pilot studies utilizing RFID tags on pharmaceutical products. These pilot activities of our members are helping us understand the challenges and opportunities of RFID as we work toward implementation on a broader scale on behalf of patient safety.

In our ongoing effort to assist the industry in moving toward EPC/RFID implementation, the HDMA Foundation launched a major research initiative in partnership with Rutgers University to study key issues surrounding data management and data sharing in healthcare, the key elements in advancing track and trace solutions. This is groundbreaking research that will define the business case and the safety benefits for data management and data sharing. This effort is a key component in HDMA's overall strategy to promote the industry-wide adoption of current and emerging new technologies. Phase I of the report is expected to be released by the end of 2006. Phase II of the study, which will provide a blueprint for how to most effectively share data across the supply chain, is in development now, and expected to be released in 2007.

As with any new technology, excitement can overshadow reality. Before widespread adoption of EPC/RFID can occur, business issues must first be resolved, standard real time systems have to be designed and trading partners have to integrate new technologies into current business practices and systems. Changes and processes of this magnitude involving new technology across a complex supply chain are monumental and take time to implement. Given the importance of maintaining a safe and reliable medicine supply, it is essential that this effort proceed forward in a close collaboration between the supply chain partners and government regulators.

In order for EPC/RFID to become a reality, a single, uniform approach is required. Current state-by-state pedigree requirements, however, are inconsistent and contradictory. These varying requirements divert human, technology and capital resources away from effective anti-counterfeiting solutions, and undercut efforts to systematically deploy EPC/RFID across the supply chain. Siphoning off resources to develop unproven, temporary systems in order to comply with individual state requirements is a step in the wrong direction. A uniform standard for pedigree requirements is necessary to prevent a patchwork of regulatory standards that take away from real solutions, such as EPC/RFID.

3. Alliances With Law Enforcement, Regulators and Trading Partners

Each member of the supply chain – the manufacturer, the distributor and the pharmacy – must work in tandem to ensure a safe and reliable supply of prescription drugs for patients. To this end, HDMA, the National Association of Chain Drug Stores (NACDS) and the Pharmaceutical Research and Manufacturers of American (PhRMA), cosigned a March 2, 2006 letter to FDA Associate Commissioner for Policy and Planning Randall Lutter formally stating our commitment to join together to seek industry-wide solutions to advance patient safety, supply chain security and business efficiencies. Moving forward, we will continue to work with these and other allied groups to identify additional ways our members can work together to support a more secure medicine supply chain for pateint safety.

Separately, HDMA in 2005 joined FDA's Counterfeit Alert Network (CAN). The Counterfeit Alert Network informs consumers, pharmacists, healthcare professionals, distributors and others of counterfeit drug incidents, and provides education on ways to

identify and prevent counterfeits from entering the U.S. medicine supply. As a partner in the CAN, HDMA will distribute time-sensitive FDA messages and information on specific counterfeit incidents to member distribution companies. HDMA also will provide educational messages about counterfeit drugs, as well as information needed to recognize and report suspect or counterfeit drug products to FDA.

Most recently, HDMA in June 2006 joined a partnership of law enforcement and professional pharmacy organizations using RxPATROL®, an information clearinghouse designed to collect, analyze and share information on pharmacy robberies, burglaries and theft of controlled substances. RxPATROL (Pattern Analysis Tracking Robberies and Other Losses) is designed to help pharmacists guard against potential robberies and burglaries, and to assist law enforcement efforts to apprehend and prosecute pharmacy theft suspects. As part of the partnership, HDMA has implemented a process whereby its members can report incidents of any type of theft to RxPATROL. Additionally, all HDMA members will receive a security report - developed by RxPATROL using crime trend analyses and security/vulnerability assessments - offering guidance on how to minimize the risk of theft-related crime.

4. Developing and Implementing Industry Best Practices

Finally, the entire supply chain is constantly identifying new ways to improve upon business practices that can enhance product safety. HDMA has strongly recommended that manufacturers, distributors and pharmacies all implement best business practices to further protect the integrity of the pharmaceutical supply chain.

HDMA has recommended thorough security measures, which should be conducted before beginning any business relationship. At a minimum, supply chain partners should:

1. conduct civil and criminal background checks;
2. conduct site inspections;
3. conduct ongoing PDMA compliance reviews;
4. conduct licensure review;
5. maintain a list of "at risk" products; and
6. develop corporate systems to report suspicious or counterfeit products.

Conclusion

In conclusion, HDMA members recognize the public trust placed upon them to ensure that authentic pharmaceutical products are handled, stored and ultimately, dispensed to patients safely and efficiently. We have zero tolerance for criminals who counterfeit patient medicines, and we are committed to ongoing, multi-layered strategies that further secure the supply chain and protect patient safety. We will continue to work with the FDA, state regulatory authorities and supply chain partners to maintain our focus on the safe, secure and efficient delivery of healthcare products. Securing the nation's prescription drug supply chain requires constant vigilance in cooperation with all supply chain partners – from the manufacturer, to the distributor, to the pharmacy. A combination of many approaches is required, involving uniform licensure standards, tough regulation and consistent enforcement, the use of innovative new technologies and

the adoption of best business practices. The health and safety of our nation, literally, is at stake.

HDMA appreciates this opportunity to provide the perspective of the nation's primary, full-line, full-service healthcare distributors on these critically important issues and I would be pleased to answer any questions.